



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0485]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Electronic Submission Process for Voluntary Allegations to the Center for Devices and Radiological Health

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All comments should be identified with the title "Electronic Submission Process for Voluntary Allegations to the Center for Devices and Radiological Health." Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, [PRASaff@fda.hhs.gov](mailto:PRASaff@fda.hhs.gov).

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Electronic Submission Process for Voluntary Allegations to the Center for Devices and Radiological Health--(OMB Control Number 0910-NEW)

This information collection request collects information voluntarily submitted to the Center for Devices and Radiological Health (CDRH) on actual or potential health risk concerns about a medical device or radiological product or its use. Because there has been no established guidelines or instructions on how to submit an allegation to CDRH, allegations often contain minimal information and are received via phone calls, emails, or conversationally from any CDRH staff. CDRH seeks to establish a consistent format and process for the submission of device allegations that will enhance our timeliness in receiving, assessing and evaluating voluntary allegations. The information provided in the allegations received by CDRH may be used to clarify the recurrence or emergence of significant device-related risks to the general public and the need to initiate educational outreach or regulatory action to minimize or mitigate identified risks.

In the Federal Register of May 6, 2013 (78 FR 26373), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden<sup>1</sup>

Allegation Reporting Respondent	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
	700	1	700	.25 (15 minutes)	175

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: May 16, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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